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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,258	12/05/2001	Kemin Zhou	3418	1011

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EXAMINER

SMITH, CAROLYN L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,258

Applicant(s)

ZHOU, KEMIN

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004 and 07 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20 and 22 is/are rejected.
- 7) ☒ Claim(s) 21 and 23-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 1/22/04 and 4/7/04, are acknowledged.

Canceled claims 1-17 and 33-51, amended claims 18, 20, and 28 are acknowledged.

Applicant's arguments, filed 1/22/04 and 4/7/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 18-32 are herein under examination.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 18, 19, 20, and 22 is maintained and necessitated by amendment under 35 U.S.C. 102(a) as being anticipated by Pugh et al. (Genome Biology, 2001, Volume 2(4), pages 1013.1-1013.3).

This rejection is maintained (claims 19, 20, and 22), necessitated by amendment (amended claim 18), and reiterated for reasons of record.

Pugh et al. disclose binding transcription factors to their DNA on a genomic-wide scale in yeast as a biological sample (p. 1013.1, col. 1, second paragraph) which represents a profile of such binding. Pugh et al. disclose using chromatin immunoprecipitation (ChIP) assay and DNA microarrays (p. 1013.1, col. 1, second paragraph). The instant specification defines a “candidate fragment” as “a nucleic acid fragment that contains information about protein nucleic acid interactions” (paragraph 0022). Pugh et al. disclose the covalently cross-linking proteins to DNA (a well known form of *in vivo* footprinting), purifying the crosslinked DNA via antibodies (elimination of unbound genomic DNA), fluorescently labeling the enriched DNA fragments (“candidate fragments”), and detecting them via hybridization to DNA probes on a glass slide (p. 1013.1, col. 1, third paragraph to col. 2, first paragraph) as stated in claims 18, 19, 20, and 22. Pugh et al. disclose various transcription factors binding to genomic regions (page 1013.2, col. 2, second paragraph) which represents DNA bound by a plurality of proteins. Pugh et al. disclose 10 regions were bound by Gal4, 29 regions were bound by Ste12, 163 regions were bound by Swi4, and 87 regions were bound by MBF transcription factor (page 1013.2, col. 2, second paragraph) wherein the later two data figures represent at least 50 proteins binding to genomic regions. Pugh et al. disclose the use of intergenic and intragenic (open reading frame) probes (p. 1013.1, col. 2, first paragraph) which means the genomic sequences of interest contain genic regions. Pugh et al. disclose genome-wide location analysis coupled with gene-expression profiling and searches for consensus sites will potentially identify direct effectors of complex gene expression program (p. 1013.3, col. 1, third paragraph).

Thus, Pugh et al. anticipate claims 18, 19, 20, and 22.

The rejection of claims 18, 19, 20, and 22 is maintained and necessitated by amendment under 35 U.S.C. 102(a) as being anticipated by Ren et al. (Science, 2000, Volume 290, pages 2306-2309).

This rejection is maintained (claims 19, 20, and 22), necessitated by amendment (amended claim 18), and reiterated for reasons of record.

Ren et al. disclose a microarray method for obtaining a profile of protein binding to genomic DNA of a biological sample from yeast and determining the location of the DNA-bound proteins (abstract). Ren et al. disclose a method that monitors protein-DNA interactions across the entire yeast genome (p. 2306, col. 1, second paragraph). Ren et al. disclose using chromatin immunoprecipitation (ChIP) with DNA microarray technology (p. 2306, col. 1, second paragraph to col. 2, first paragraph). Ren et al. disclose DNA fragments are cross-linked to protein (a well known form of footprinting), enriched by immunoprecipitation of the crosslinked DNA with antibodies and subjecting them to a different fluorescent label than the unenriched (unbound DNA) [elimination of unbound DNA from bound-DNA labeling], and hybridized to a microarray containing yeast intergenic sequences (p. 2306, col. 2, first paragraph). Ren et al. disclose 10 genes being regulated by Gal4 proteins (page 2306, col. 3, first paragraph) which represents a plurality of proteins bound to DNA. Ren et al. disclose more than 200 genes are transcription activated in a Ste12-dependent fashion with 29 genes being directly regulated by Ste12 (page 2307, col. 2, second paragraph to col. 3, first paragraph) which represents at least 50 proteins bound to DNA. Ren et al. disclose a scanned image of a microarray containing a detectable red intensity identifying DNA bound to protein (Figure A). Ren et al. disclose this location profiling and expression profiles aided in the identification previously unknown functions of proteins

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(Gal4 and Ste12) (abstract). Ren et al. disclose using the combination of genome-wide location and expression analysis to identify global sets of genes controlled by transcriptional activators (p. 2308, col. 3, second paragraph). Ren et al. disclose proteins including some with unknown function (Figure 3A).

Thus, Ren et al. anticipate claims 18-20 and 22.

Applicants state the Pugh et al. and Ren et al. references are concerned with obtaining individual profiles while the instant invention is directed to obtaining profiles of a plurality of proteins on a genome-wide scale in high-throughput format. This statement is found unpersuasive as nowhere in instant independent claim 18 is there any mention of obtaining multiple profiles. It is also noted that the plurality of proteins that are bound to DNA are not necessarily different type proteins. These proteins could be at least 50 of the same type proteins. Therefore, the Pugh et al. and Ren et al. prior art are still valid references in 35 USC 102(a) rejections, as detailed above.

Conclusion

No claim is allowed.

Claims 21 and 23-32 are objected to as being dependent upon a rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

May 6, 2004

Ardin H. Marschel 5/9/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER